Remarks/Arguments

Claims 1-20 (all claims originally presented) have been rejected under 35 USC 102(b) and/or 35USC 103 (a) over a group of references, all of which were cited by applicant.

Claims 6, 8, 10, 14, 15 and 17 are cancelled by this amendment.

Claims 1,2, 9 and 16 and 20 are herewith presented in amended form.

In Claim 2 a period has been added at the end of the claim, and limitations have been added to Claims 1, 9, 16 and 20.

Claims 3-5, 7, 11-13 and 18 an 19 are presented in original form.

It is believed that the amendments to independent claims 1, 16 and 20 have placed them and the remaining currently presented dependent claims in condition for allowance.

Argument

Claim 1, as currently presented, is narrowly focused on the details of the optical source utilized to generate the radiation emitted by the blood present in the sterile matrix of the nail. In addition, the emitted radiation being analyzed is limited to the Stokes Raman. As is apparent from the specification these limitations provide critical and unobvious advantages compared to prior art analytical techniques described in the references. A critical point applicable to all the references (both 102 and 103), with the sole exception of Wach et. al is that they deal with one or more types of absorption spectroscopy and require transmission of radiation through the portion of the body being analyzed. Raman spectroscopy does not and indeed cannot be used to detect analytes by passing radiation through a sample.

The cited 102 (b) references will now be discussed and are believed to be clearly distinguishable for the following reasons:

- Clarke et al USP 5,222,496 teaches use of a <u>plurality</u> of wavelengths and reflection absorption spectroscopy (see e.g., col. 5, lines 14-21). Applicant claims using a <u>fixed</u> wavelength and Stokes Raman spectroscopy.
- 2. Wach et al USP 6,370,406 does mention Raman spectroscopy but describes the detection of e.g. particles of matter present in a volume <u>bordered by reflective surfaces</u>. Moreover, its entire focus is on the use of an optic fiber probe (see e.g., col. 13, line 66 to col. 14, line 6). Applicants invention does not utilize a plurality of reflective surfaces but in contradistinction utilizes reflection by the analyte itself (e.g., glucose).
- Aldrich, USP 6,064,898 does not anticipate or render obvious applicants claimed invention. It does not remotely suggest Raman (or indeed any reflective) spectroscopy. As can be seen from Figure 1 of the '898 patent and at Col. 6 lines 34-35, the light is transmitted through the finger.

With respect to the 103 (a) rejections, Applicant comments as follows:

- The combination of the previously discussed Clarke et al and Wach et al patents does not render obvious applicants Claims 16, 18 and 19. Again, Clarke teaches transmission through the finger and absorption spectroscopy. Component 51 of Figure 3A is a retraining clip not a film (see col 6, line 38). No reason to combine the teaching of these two patents is apparent since they involve totally distinct spectroscopic techniques.
- 2. The Jobsis '645 patent in combination with Aldrich does not render claim 7 obvious. Jobsis teaches a laser light source for the monitoring of metabolism using optical tomography. Again, the light is transmitted <u>through</u> the subject and not reflected as is done with Raman Spectroscopy.
- 3. The Boppart et al '413 patent again teaches optical coherence tomography (OCT) and non-retroflective forward scanning OCT. These techniques have no relationship with Raman Spectroscopy. They utilize an incoherent light source and require transmission through the sample (see Fig. 2).
- 4. Claim 20 has been rejected under 35USC 103(a) as unpatentable over a combination of the Misner et al '189 patent and the Lepper et al '262 patent. Claim 20 as presently amended is clearly limited to Raman Spectroscopy. Both the '189 and '262 patents describe light transmitted through the fingers. No basis exists for assuming that the technology described or suggested by either of these patents would, or even could, be useful in Raman Spectroscopy.

Applicant does not claim to have been the first inventor to suggest non-invasive spectroscopy for detecting analytes such as glucose inside the human body. Rather applicant has specifically discovered the unexpected advantages of using a CW, fixed wavelength laser emitting within a specific wavelength range and collecting Stokes Raman optical radiation emitted by blood from the sterile matrix

under the nail. None of the cited references, either singly or in combination, teach or suggest this specific analytical technique.

It is therefore requested that the Examiner reconsider his rejection and pass the currently presented claims to allowance.

Respectfully Submitted,

Herbert G. Burkard, Esq.

#24,500

Attorney for Applicants

3350 Scott Blvd Bldg 1

Santa Clara, CA 95054